

## **REMARKS**

Careful consideration has been given by the applicants to the Examiner's comments and rejection of the claims, as set forth in the outstanding Office Action, and favorable reconsideration and allowance of the application, as amended, is earnestly solicited.

Applicants note the Examiner's comments that the drawings are lacking from the application in the official files, however, applicants note that the required drawings were submitted with the original application, which was filed in the French language on October 20, 2000, as also acknowledged by the application branch.

However, inasmuch as the Examiner apparently cannot locate the drawings, applicants herewith enclose an additional copy of the two (2) sheets of drawings, containing the required Figures 1a through 6.

Applicants further note the Examiner's objections to the Abstract of the Disclosure, and applicants herewith submit, on a separate sheet attached herewith, a new Abstract of the Disclosure, which is deemed to be in conformance with the requirements set forth in the Office Action.

Applicants further note the rejection of Claims 1 and 4 under 35 U.S.C. §102(b) as being anticipated by Gustafsson, U.S. Patent No. 4,473,421; and the rejection of Claim 3 under 35 U.S.C. §103(a) as being unpatentable over Gustafsson, as detailed in the Office Action; furthermore, Claim 2 has been rejected as being unpatentable over Gustafsson and further in view of Swanson, U.S. Patent No. 5,376,127, as also detailed in the Office Action.

Accordingly, in order to clearly and unambiguously distinguish over the art, applicants have cancelled the elected claims, Claims 1-4, without prejudice, and in lieu thereof herewith present new Claims 8-10, which are deemed to define the invention in clear and precise terminology, pursuant to the

U.S. practice, while patentably distinguishing over the art, irrespective as to whether the latter is considered singly or in combination. In particular, applicants note that newly presented Claim 8 comprises essentially a combination of cancelled Claims 1 and 2 and are further amended in conformance with the U.S. practice.

Reverting in particular to the art as applied to the claims, applicants submit the following comments in traverse thereof:

Basically, the present invention is directed to a process for manufacturing a flexible sleeve for a prosthesis or an orthosis, wherein the sleeve is adapted to be positioned between a stump or a replica of a stump, while defining the patient's limb and a prosthesis or an orthosis of the patient. The sleeve is, thus, constituted of a flexible thermoformable material.

Pursuant to the inventive process, a preform of the sleeve is heated until it softens and then slipped over the stump or replica thereof of the patient's limb, and the shape of the preform is then carefully matched to that of the stump and left to cool thereon.

This provides a flexible protective sheathing, which protects the stump against painful impacts or other frictional forces tending to injure the patient.

To the contrary, the prior art, as applied to the claims, clearly is directed to a structure that is not at all disclosed or contemplated herein.

With respect to the primary reference of record to Gustafsson, U.S. Patent No. 4,473,421, the latter discloses a rigid sleeve element which consists of a prefabricated internal sleeve formed of a transparent acrylic plastic, which is strengthened by a further layer of fiberglass or carbon fiber and plastic composition, which can be combined with a fiber and laminated externally on the inner sleeve.

This inner sleeve is manufactured by an injection molding process and in itself is not flexible providing a rigid structure, which is a support for the stump or prosthesis. To the contrary, the

present invention is of a flexible nature in the design of the sleeve positioned to conform to the shape of the stump or the stump replica, and the latter sleeve may be shaped to conform to the stump or stump replica by heating and then cooling thereof.

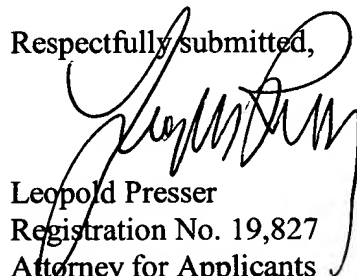
Consequently, the type of structure or prosthesis formed in Gustafsson is the opposite of a flexible protective sleeve, as defined by the present invention, and as set forth in the claims and has in no manner any applicability to the present invention.

Even combining Gustafsson with the secondary reference, Swanson, U.S. Patent No. 5,376,127, would not lead to the inventive configuration and process. Swanson is directed to the provision of a prosthesis cover or shield adapted to surround the endoskeleton of a prosthesis, which is completely different from the object of the present invention. The Swanson cover is constituted of a foam polyethylene material or lightweight ??saliothermoplastic?? and a preform of the cover is manufactured, heated to a thermoplastic state and positioned on a mold having approximately the shape of the limb, which is to be replaced by the prosthesis. A vacuum is then applied to the preform so as to conform to the shape of the mold. A cover obtained from a preform of that type, as shown in Swanson, is not adapted to be interposed between a stump and socket in order to protect the stump and consequently, cannot be employed in a manner analogous to the sleeve provided for by the present invention, which is adapted to protect the stump from impact shocks and other painful contacting friction or the like.

Accordingly, the newly presented claims, Claims 8-10 have been provided in order to emphasize the patentable distinctions and process which is not at all disclosed in either of the cited reference, nor any of the other art referred to by the Examiner or known to the applicants.

Inasmuch as the applicants have provided claims which are deemed to be clearly and patentably distinct over the art, the early and favorable reconsideration and allowance of the application, as amended, is earnestly solicited. However, in the event that the Examiner has any queries concerning the instantly submitted Amendment, applicants' attorney respectfully requests that he be accorded the courtesy of possibly a telephone conference to discuss any matters in need of attention.

Respectfully submitted,



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Enclosures: Formal Drawings (2 Sheets) and New Abstract of the Disclosure